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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/647,952
Filing Date: December 06, 2000
Appellant(s): GAL-ON, AMIT

Mark M. Friedman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 17 January 2006 appealing from the Office action mailed 19 May 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement declaring that there are no related appeals and interferences in this case is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments

The appellant's statement of the status of amendments contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Appellant's brief presents arguments relating to objections to claims 6, 11, 12 and 20 according to 37 CFR § 1.75 (c) and MPEP § 608.01 (n) as failing to meet the requirement for alternative language.

This issue relates to petitionable subject matter under 37 CFR 1.181 and not to appealable subject matter. See MPEP § 1002 and § 1201.

(7) Grouping of Claims

Appellant 's brief includes a statement that claims 6, 11, 12 and 20 are grouped together for the purpose of the objections. Note is made about these objections in the above paragraph. They will not be further dealt with.

Appellant's brief includes a statement that claim 1, 2, 11 and 15 are grouped together, that dependent claims 6, 10, 12 and 20 are each grouped separately. However, appellant does not provide reasons why the claims of 6, 10, 12 and 20 are separately patentable, as set forth in s(37 CFR 1.192(c)(7) and (c)(8). "Merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable"(CFR 1.192(c)(7)).

(8) Claims Appealed.

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal:

Rieger, *et. al. Glossary of Genetics and Cytogenetics*, (New York, Springer-Verlag, 1976), page 377.

Huet, *et al. J. General Virology,* Vol. 75, (1994), pages 1407-1414.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 USC 112(2): Claims 1, 2, 6, 10-12, 15 and 20.

Claims 1, 2, 6, 10-12, 15 and 20 on appeal stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that they do not particularly point out and distinctly claim the subject matter which Appellant regards as the invention. In claim 1, line 3, and all claims dependent thereon, "single mutation" is indefinite because the frame of reference is not specified. See Rieger, et. al., Glossary of Genetics and Cytogenetics, 1976, page 377, stating that the standard of reference for a mutant is the so-called wild-type, either the state of organisms as they are found in nature or arbitrarily chosen. In the present case, it is unclear what would be considered a single mutation, because it is unclear what sequence has been mutated. And the specification fails to define or clarify what would be considered the "wild-type".

35 USC 102(b): Claims 1, 2, 6, 10-12, 15 and 20

Claims 1, 2, 6, 10-12,15 and 20 on appeal stand rejected under 35 U.S.C. 102(b) as being anticipated by Huet, et al. (Mutations in the helper component protease gene of zucchini yellow mosaic virus affect its ability to mediate aphid transmissibility. J. General Virology, vol. 75, 1994, pages 1407-1414).

Appellant's claims are drawn to a recombinant potyvirus infectious nucleic acid construct useful in plant cross protection, the construct comprising a full length clone

"characterized" by a single mutation, said single mutation residing in its HC-Pro gene conserved FRNK box encoding said single mutation comprising a substitution of Arg by Ile; wherein the construct is capable of systemic infection of a plant; wherein said systemic infection induces a mild form of disease; and wherein said systemic infection affords cross protection against a subsequent potyvirus infection. Dependent claims are drawn to the construct wherein the nucleic acid is cDNA or RNA, wherein the potyvirus is ZYMV, wherein the cross protection is against severe strains of ZYMV, and to the construct further useful for the transient expression of foreign nucleic acid in plants; wherein the full length clone has, in any position, a sequence of DNA or RNA inserted into the full length clone. Appellant also claims a method for introducing foreign nucleic acid into plants comprising infecting a plant with a recombinant potyvirus infection nucleic acid construct as described above, as well as a composition for plant inoculation or for transient expression of foreign nucleic acid in plants containing, as an active ingredient, the recombinant construct of any of the above claims.

The wording "characterized by" does not exclude that the full length clone contains in addition, substitutions at any other position of the virus. In claim 1, line 3, and all claims dependent thereon, "single mutation" is indefinite because the frame of reference is not specified. In the present case, it is unclear what would be considered a single mutation, because it is unclear what sequence has been mutated. And the specification fails to define or clarify what would be considered the "wild-type". Furthermore, claim 1 is written in "comprising" language, and therefore is not exclusive.

Huet teaches a recombinant potyvirus infectious nucleic acid construct comprising a full length clone (pZYMC-HC (G1-T)) having its HC-Pro conserved FRNK box containing a substitution (Figure 1(b) last bar, p. 1408, details the full length clone of ZYMV-HC with a FRNK box substitution), where the substitution is of Ile for Arg (Figure 2, p 1410), where the potyvirus is ZYMV (Figure 2, legend, line 1), where the nucleic acid is a cDNA (Figure 1, page 1408, 1st line of legend), and a recombinant potyvirus PPV (p1410, Figure 2).

Huet further teaches a recombinant construct where the full length clone has a sequence of DNA or RNA inserted into the full length clone (Figure 1, pg 1408, line 3 of legend, detailing the T7 promoter insertion), a method for introducing a foreign nucleic acid into plants by infecting a plant with a full length clone (p1409, last paragraph), and using the recited nucleic acid construct to inoculate plants and obtain progeny virus (Table 1, p 1410, and Table 2, p 1411).

(11) Response to Argument

It is respectfully submitted that Appellants' arguments are not persuasive of error in the Examiner's position, as stated below.

with regard to 35 USC 112(2): Claims 1, 2, 6, 10-12, 15 and 20.

In the Appeal Brief (p.11), Applicant refers to an extended Applicant-initiated telephonic interview of 30 June 2004 for which there is no complete written record. See Supplemental Appeal Brief Appendix A (05 September 2005) provided by the Appellant.

In the Appellant's summary and discussion of this interview, Appellant raises certain issues which are misleading and which misrepresent the facts. Appellant further asserts that the Examiner is unable to "grasp the state of the art and the level of knowledge of one skilled in the art at the time the application was filed "(¶ bridging p.12-p.13 of the Supplemental Appeal Brief).

The issues are: the Balint, 1990, reference) [The nucleotide sequence of the zucchini yellow mosaic virus. Proceeding of the VIIIth International Congress of Virology (Abstract), 1990, Berlin, p.472].

(a) The Balint, 1990 reference. Applicant first presented the Balint, 1990, reference in this 30 June 2004 interview and gave the relevance of it (see p. 3 Supplemental Appeal Brief Appendix A). The Office did not uncover the Balint reference.

However, in the Appeal Brief (sentence bridging pages 11 and 12), Appellant *asserts that the Balint, 1990, reference was "uncovered by the Examiner in the course of examination indicates that no undue effort is required to find it".* Appellant further alleges (page 11 of the Appeal Brief, bottom ¶): "one of ordinary skill in the art, such as Huet, would have been able, without undue effort, to obtain the wild-type sequence published by Balint for purposes of ascertaining if the claimed "single mutation" criteria were being met by a disputed ZYMV strain."

Appellant's arguments are unpersuasive and factually incorrect. The Balint , 1990, reference was not found by the Examiner during examination. The opposite is

true. Rather Appellant informed the Examiner of this reference during the telephone interview of 30 June 2004. See Appeal Brief, p. 11, 3rd ¶, where Appellant admits that "the Examiner was made aware [of] ...Balint et. al. (1990)."

(b) The relevance of Balint. Applicant presents Balint as providing "the wild-type sequence "[ZYMV], which gives the frame of reference.

Appellants' argument is unpersuasive and disingenuous. *Balint gives no sequence information, written or electronic, of any virus.* Furthermore, the Balint reference is an Abstract, and as such, presents very limited information.

Appellant asserts that during the telephone interview, Appellant informed Examiner that Huet, 1994, op. cit. "cited in 1994, a published wild-type sequence of ZYMV" namely Balint et. al. ,1990, [The nucleotide sequence of the zucchini yellow mosaic virus. Proceeding of the VIIIth International Congress of Virology (Abstract), 1990, Berlin, p.472]. Appellant asserts that "Huet's reference to Balint (1990) indicates that the required frame of reference for claim 6 and all claims which depend therefrom was widely available and generally acknowledged by those of one of ordinary skill in the art at the time the instant application was filed". Appellant further asserts that the "fact that the Balint reference was uncovered by the Examiner in the course of examination indicates that no undue effort is required to find it". See paragraph bridging pages 11 and 12 of the Appeal Brief.

Appellant asserts that, even though Balint does not provide electronic sequence information, "the full sequence was first published in 1995 [Wisler et. al. 'Characterization of the P1 protein and coding region of the zucchini yellow mosaic

virus', J. General Virology, vol, 76, pages 37-45 (1995) [Accession No. L31350]", and that this publication made the required frame of reference "even more readily available". See page 12 of the Appeal Brief, first full paragraph.

Appellant asserts that only in the current (most recent) Office Action did it become clear that the frame of reference is being requested for the entire genomic sequence, and the Appellant notes that "for the record, the currently pending Office Action contains no request for a SEQ ID NO:". See page 13, of the Appeal Brief, second full paragraph.

The Examiner maintains that the Office has previously requested clarification for the "substitution". See page 3 of the Office Action of 30 July 2003. Applicant's amendment of 30 April 2003 to claim 1 recited " a full length clone characterized by a single mutation..", which Applicant, asserted (p. 3) "means one only, one and no more". Applicant's traversal was deemed unpersuasive. The Examiner responded: "there is no reference point to discriminate what is different one from the other. Applicant needs a SEQ ID NO: or definite frame of reference."

Appellant's statement alleging the Examiner's "inability to grasp the state of the art and the level of knowledge of one of ordinary skill in the art the time" of filing is discourteous and without merit.

Furthermore, Appellants' own specification contributes to the confusion regarding the starting point for the claimed single mutation. On page 4 of the specification, first full paragraph, it is stated that:

Preferably, the construct further contains a substitution which effectively abolishes aphid transmissibility, such as a substitution of the Ala residue at position 10

in the conserved DAG triplet in the N-terminal region of the CP or substitution of Thr at position 309 in the HC-Pro in ZYMV.

Thus Appellant characterizes their invention as encompassing two, not one, mutations.

Furthermore, Appellants' specification characterizes the starting material, in which the Arg 180 was replaced with Ile, *as already containing an additional mutation at position 148* (see page 10, bottom paragraph). Thus Appellant admits that the starting material for their Arg to Ile mutation already contained an additional Asp 148 substitution, rather than the wild-type sequence allegedly taught by Balint et. al.

with regard to 35 USC 102(b): Claims 1, 2, 6, 10-12, 15 and 20.

Appellant has not argued the § 102(b) rejection of independent claim 1 and dependent claims 2, 11, and 15, "because the Applicant has not overcome the §112 second paragraph rejections" of those claims (Brief, p. 13). The Appellant argues the rejections of "dependent claims 6 and 10 and those portions of claims 12 and 20 which depend therefrom", saying that the previous rejection over Huet "induced the Applicant to offer substantive amendments which greatly reduced the scope of the claimed invention. Specifically, the phrase "a single mutation" meaning one and only one mutation was introduced into claim 1" (Brief, p.14).

Appellant further asserts that Huet teaches against what is claimed because Huet teaches a ZYMV strain characterized by two mutations. Appellant further argues

that "Huet observed certain properties in a mutant strain with two mutations", but that "Huet does not hint or fairly suggest that the Arg to Ile mutation in the FRNK box alone is necessary or desirable to produce 'a construct capable of systemic infection of a plant; wherein said systemic infection induces a mild form of disease, and wherein the systemic infection affords cross protection against subsequent potyvirus infection' as instantly claimed."

The Examiner maintains that Huet et. al. teach all elements of the claimed recombinant virus infectious nucleic acid construct. As recited in claim 1, Huet et. al. teach a construct "characterized by a ...single mutation, said single mutation residing in its HC-Pro gene conserved FRNK box encoding sequence" which encodes "a substitution of Arg by Ile". As claimed in claim 6, Huet et. al. teach that this mutation is in a ZYMV nucleic acid, which is "infectious" and "capable of systemic infection" as claimed in claim 1.

While Huet et. al. teach that their ZYMV nucleic acid additionally comprises a mutation which substituted Gly for Asp *"in a non-conserved region"* (see page 1407, Abstract), this substitution does not occur in the HC-Pro gene conserved FRNK box as claimed. Given the open claim language and Appellants' own specification as discussed above, additional mutations outside of the FRNK box are encompassed by Appellants' invention.

Furthermore, the ability of the construct taught by Huet et. al. to confer cross protection would have been inherent, since Huet et. al. teach a construct with all the structural features of that taught by Appellant.

Regarding product claims 1, 2, 6, 10, 12 and 20, see *In re Cruciferous Sprout Litigation,* 64 USPQ2d 1202, (Fed. Cir. 2002), which teaches that newly recognized constituents or properties of a prior art product are inherent properties which do not render claims to that product patentable.

Regarding process claim 15, see *Integra Life Sciences I Ltd. v. Merck KGaA,* 50 USPQ2d 1846 (DC SCalif, 1999) which teaches that a reference teaching a process may anticipate claims drawn to a method comprising the same process steps, despite the recitation of a different intended use in the preamble or the later discovery of a particular property of one of the starting materials or end products. See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993), which teaches that a reference teaching a claimed process, wherein one of the claimed properties of a product used in the prior art process is inherent but undisclosed by the reference, may be properly applied as art against the claimed process.

Accordingly Huet anticipates the claimed invention.

Conclusion

Accordingly, it is considered that the invention encompassed by claims 1, 2, 6, 10-12, 15 and 20 on appeal has not been particularly and distinctly claimed; and that the invention encompassed by claims 1, 2, 6, 10-12, 15 and 20 on appeal is anticipated by Huet et. al.

Thus is considered that the position of the Examiner is sound and should be AFFIRMED.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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